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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,916	09/18/2003	Ernest J. Friedlander	07414.0107-00000	7069

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Finnegan, Henderson, Farabow,
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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,916	FRIEDLANDER ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/25/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. Claims 1-10 are currently pending. Claims 1-10 are considered for examination in this office action. The Preliminary Amendment filed on February 25, 2004 has been entered.

Priority

2. This application filed on September 18, 2003 claims benefit of US provisional 60/412,480 filed on 9/19/2002.

Information Disclosure Statement

3. The Information Disclosure Statement filed on June 22, 2004 has been entered and considered.

Claim Interpretation

4. According to MPEP 2112.01 "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The following rejections are based on the fact that the composition used in the instant invention and the composition in the prior art are identical and should have similar properties according to MPEP 2112.01. Thus the composition of the prior art would have the function of fragmenting DNA in similar composition and similar conditions.

Further in the instant specification the term "substantially free of nuclease" is defined as a composition in which there is insufficient nuclease to effect substantial fragmentation of the

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DNA, and substantial DNA fragmentation is defined as at least 20-50% DNA fragmentation,

Claim interpretation: In the following rejections, the composition that is substantially free of nuclease is broadly interpreted as the composition comprising sterile water or buffer alone or a buffer comprising a chelating agent such as EDTA or EGTA. Further in the instant specification the term “substantially free of nuclease” is defined as a composition in which there is insufficient nuclease to effect substantial fragmentation of the DNA, and substantial DNA fragmentation is defined as at least 20-50% DNA fragmentation, which is interpreted as the DNA fragmentation is partial or incomplete in a composition comprising an insufficient nuclease. Thus lysis or degradation or denaturation at temperature above 90⁰ C is considered as fragmenting. In the light of the instant specification the term “quantitation” is broadly interpreted as quantitation by gel electrophoresis or quantitation by PCR.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Eggerding (USPN. 5,912,148).

Eggerding teaches a method of claim 1, comprising incubating DNA above 90⁰ C in a composition (TE buffer or sterile water) that is free of nuclease (see col. 11, line 10-15, indicates that the DNA is boiled (100⁰ C) in a sterile (nuclease free) water for 20 min, which meets the limitation in the instant claim 1 and also would have similar function of fragmenting DNA, since

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the composition and conditions are same, see also col. 11, line 3-5 indicating that the DNA is dissolved in small volumes of Tris-EDTA buffer, pH 8.0 and the same 2ul of DNA is used in amplification reactions and is heated at 94⁰ C for 5 min for denaturation (fragmenting) see col. 15, line 18-20, col. 16, line 1, which meets the limitations in claim 1, since the claim 1 is in “comprising “ open language format).

With regard to claims 2-3, Eggerding teaches that the DNA is in a solution (buffer) comprising 10mM Tris and 1mM EDTA, pH 8.0 (see col. 11, line 3-5);

With regard to claims 4-5, Eggerding teaches that the incubation lasts between 5 and 60 minutes (see col. 11, line 10-13, col. 16, line 1);

With regard to claim 6, Eggerding teaches that the DNA is quantitated after fragmentation (boiling) (see col. 15, line 18-20, col. 16, line 1-3, quantitation by PCR);

With regard to claims 7-8, Eggerding teaches that the composition comprises a fluorescent dye indicator (see col. 8, line 23-60);

With regard to claims 9-10, Eggerding teaches a method of determining the presence or absence of a DNA sequence and determining the quantity of a DNA sequence in a sample comprising

(a) generating a quantity of fragmented DNA comprising the nucleic acid above 90⁰ C in a thermal cycling apparatus (thermocycler) in a composition that is substantially free of nuclease (see col. 15, line 15-30, col. 16, line 1);

(b) quantitating the fragmented DNA (see col 16, line 2-3)

(c) and performing an oligonucleotide ligation assay (see col. 16, line 3-7);

(d) determining the presence or absence of the DNA sequence and quantity of the DNA sequence from the oligonucleotide ligation assay (see col. 16, line 8-25). Thus the disclosure of Eggerding meets the limitations in the instant claims.

B. Claims 1-2, 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Down et al. (USPN. 5,766,852, reference taken from IDS submitted by the Applicants).

Down et al. teach a method of claim 1, for fragmenting DNA (lysis or degradation or fragmentation, see col. 5, line 45-47, col. 2, line 41-) comprising

(a) incubating the DNA (mycobacteria sample comprising DNA) above 90⁰ C in a composition that is substantially free of nuclease (see col. 8, line 33-42, col. 5, line 45-67, col. 6, 1-17, col. 7, line 10-20, line 50-52, indicates that the composition comprising a buffer alone or DTT results in DNA fragmentation, and the composition comprising EDTA (depending on the concentration of EDTA used) results in partial or incomplete DNA fragmentation or reduces the degradation of DNA, which indicates substantial fragmentation of DNA).

With regard to claim 2, Down et al. teach that the DNA is in a solution (buffer) comprising 10mM Tris (see col. 2, line 60-67) and 1mM EDTA (see col. 3, line 10-20, indicates EDTA concentration ranging from 1mM to 10mM);

With regard to claims 4-5, Down et al. teach that the incubation lasts between 5 and 60 minutes (see col. 2, line 50-54, col. 5, line 45-62-67, col. 7, line 10-54);

With regard to claim 6-7, Down et al. teach DNA quantitation after fragmentation by gel electrophoresis using a fluorescent indicator (ethidium bromide) and southern blot quantitated using autoradiography (see 39-51, col. 5, line 62-65);

With regard to claim 8, Down et al. teach that the fluorescent indicator comprises a fluorescent dye (ethidium bromide) (see col. 5, line 62-67, col. 6, line 1-5).

Thus the disclosure of Down et al. meets the limitations in the instant claims.


Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Suryaprabha Chunduru 3/18/05
Examiner
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